VES-MATIC CUBE 80

Installation Guide

Revision 2.00 of 04/11/2009

English

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SUMMARY

1. Technical Specifications

Power supply	Europe: 230Vac@50Hz; Usa/Canada: 110-120Vac@60Hz	
Absorbed electrical power	265VA	
Fuses	2 x 5,0A T (5 x 20 mm) UL-CSA	
Dimensions	650 x 580 x 690 mm (l x h x p)	
Weight	45 Kg	
Ambient temperature	Operational	from +15 to +35°C
	Storage	from + 5°C to + 45°C
Relative humidity threshold	from 20 to 80% without condensation	
Central unit	Freescale i.MX31 ARM11 Microprocessor; Flash 128MB NAND; 128 MB DDR RAM	
Display	TFT 800x 600 colours with Touch Screen	
Peripheral control unit	Microprocessor board on host Bus	
Internal analytical section	Chain with 89 positions for the relative test tubes	
Chain advancing step	19 seconds in the analytical cycle	
Sample insertion section	10 + 10 sliding blocks for housing and transporting the typical haematology racks	
Analysed sample collection section	Sample-holder racks with 8x14 positions for storing processed test tubes.	
Optical units	Two pairs of opto-electronic units (Led & Analogue Sensor).	
Printer	Alphanumerical with thermal paper 58 mm wide, 36 characters per row, speed 20 mm/sec.	
Interfaces	2 x RS232C, 2 USB Host, 1 USB Client, 1 Slot Compact Flash	
Protection Category	CLASS I	
Safety standards	CEI EN 61010-1 (Ed.2001-11); CAN/CSA-C22.2 No.61010-1-04 (Ed.2004-07); UL61010-1 (Ed.2004-07)	
EMC	CEI EN 61326 (Ed.2004-08)	
Installation category	II	

The safety and performance standards of the instrument are not guaranteed in the case of a different power supply cable from the one supplied being used with the instrument.

2. Storage and Transport

<u>Given the size and weight of the device, any movement of the instrument has to be executed by at least two people.</u>

The Vesmatic Cube 80 is a precision instrument and has to be handled as such. Inappropriate handling can harm the internal components and cause mechanical damage.

For the storage and handling of the instrument, the environmental conditions specified in paragraph 1 must be strictly adhered.

Given the size and weight of the machine, the transportation has to be carried out using all precautions necessary, to avoid jarring and excessive inclination that could damage the instrument

PACKAGE DIMENSIONS

WIDTH (box)	cm	80
HEIGHT (box)	cm	84
DEPTH (box)	cm	80
GROSS WEIGHT (including EuroPallet)	kg	75
PACKAGING WEIGHT (including EuroPallet)	kg	8

<u>Keep the original packaging complete with internal parts, for all subsequent transportation of the instrument.</u>

3. Preparation and Checks Before Installation

The following conditions must be enforced for the safety of the instrument and the operator:

The power network (installation category II) must be compatible with the electrical requirements, specifications and current indicated on the electric power plate supplied with the instrument; it is advised that the efficiency of the electrical system is periodically verified.
The network and relative outlets have to be out-fitted with an efficient ground connection following the laws in force in the matter of electrical systems.

Before making the connections with external instruments (Pc, Barcode Reader), <u>remember to always do this while the instrument is switched off</u>, it is necessary to verify compatibility (see the relative user manual) with the specifics indicated in chapter 7 of the Operator Manual and verify that the ground connection between them is uninterrupted. Connection with an external PC is possible with specific software (Activesink)

The operator has to be trained to ensure awareness of proper procedures, restrictions and warnings indicated in this guide in addition to the required individual laboratory safety procedures.

The material for the security of the operator (gloves, container for the disposal of the consumables used, cleaning solutions for the cleaning of the instrument) has to be always available.

The collocation of the instrument has to follow the guidelines indicated in paragraph 5.

<u>IT IS ABSOLUTELY PROHIBITED</u> to remove or modify the security and protection devices of the instrument.

4. UNPACKING

Given the size and weight of the device, any movement of the instrument has to be executed by at least two people
During the movement of the device avoid jarring and excessive inclination that could damage the instrument.

Unpacking of the instrument

Execute the phase of unpacking as described and shown below:

1. **Remove the screws of the wood box:**

Fig. 4.1

2. **Remove the cap of the box**

Fig. 4.2

3. **Slide the box up from the top (see lateral adhesive)**
4. **Remove the manual and the accessories contained in the box**
5. **Remove the base of the accessory compartment “A”, (Fig. 3.5), the 4 lateral protections “B” (Fig 4.3) and the nylon bag that covers the instrument.**

Fig. 4.3

6. Apply the supplied handles to the instrument to execute the transfer of the instrument, as shown in sequence (Fig.4.4)

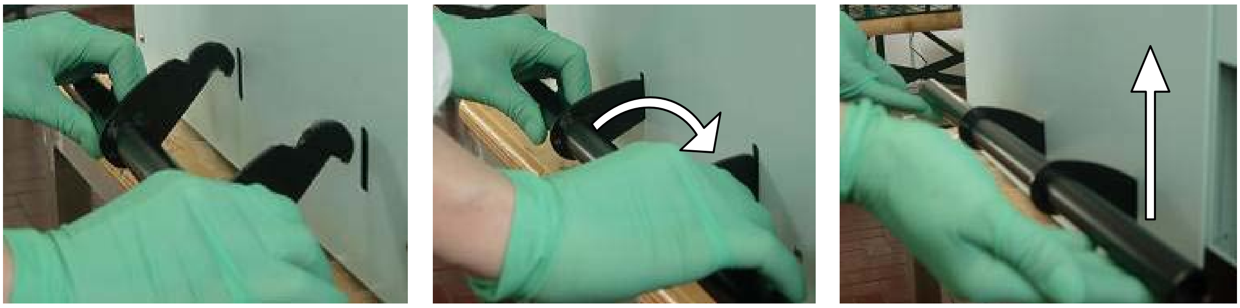
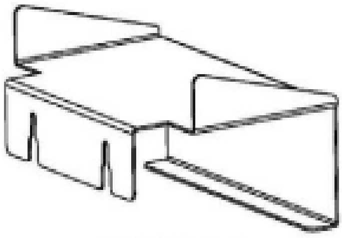


Fig. 4.4

7. Check that the packing list corresponds with the supplied material.

Should the instrument and/or the accessories supplied turn out to be damaged during transport, notify the delivery personnel and the Assistance Centre.
Should there be any missing items, notify the Assistance Centre.



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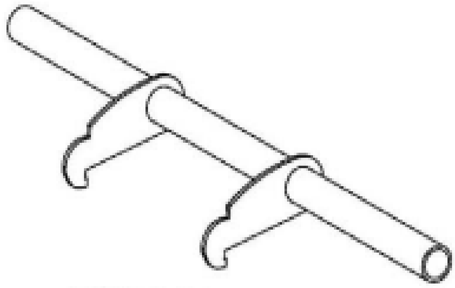
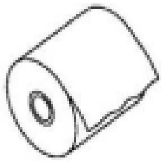


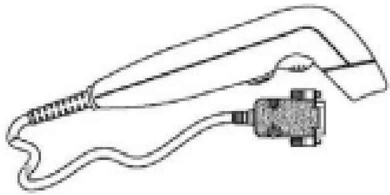
10340531 (2x)

10345960 (2x)

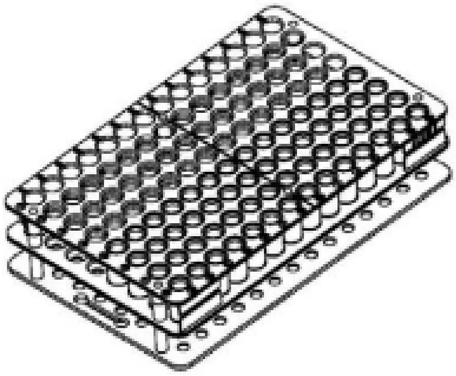
12300000 (1x)



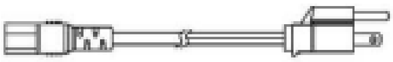
20400450 (2x)



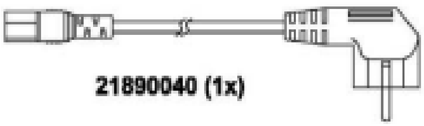
20550510 (2x)



30003720 (2x)



21890370 (1x)



21890040 (1x)

5. PLACEMENT

The environment intended for this instrument is the analysis laboratory.
For safety reasons and given the type of exams that it executes, the instrument has to be placed far from sources of heat, in zones non accessible to liquids, in environments free from dust and on perfectly flat work benches that are not subject to shocks or vibrations.
Furthermore it is advised that the VesMaticCube be placed far from possible generators of Electro magnetic waves (for example fridges, laboratory centrifuges) and from instrumentation without the CE mark, since they could affect the proper functioning of the instrument.
It is advised that a proper table be used that can support the weight of the instrument. The table or bench top should not exceed 90cm in height, to guarantee an ergonomically correct position for the operator during the input of the commands on the Tablet PC.
The table or bench top where the instrument will be placed, should allow enough space, about 40cm, on the sides of the instrument for the operator to easily introduce and extract the sample holder rack in the classifier module (Fig. 5.1)

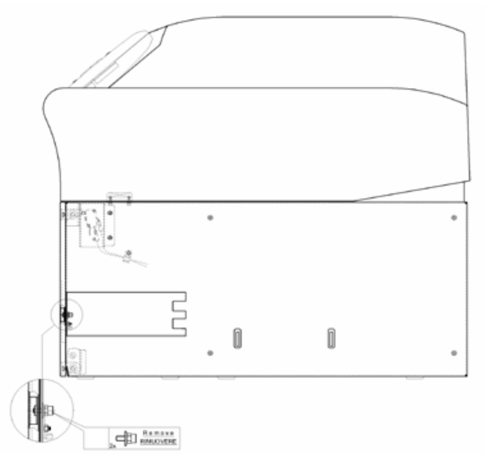
Fig. 5.1 'Frontal view with the extensions for rack input'

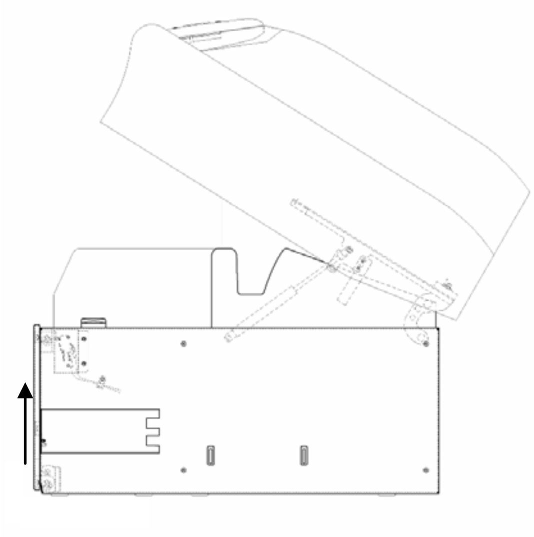
Furthermore, to be able to reach the connectors on the rear of the window and, most of all, to be able to quickly access the switch and the power cable in case of emergency, it is necessary to maintain a safe distance from the wall of at least 20 cm from the back side of the instrument.
For operator safety, do not place any materials or objects such as paper or containers on or near the instrument.
Choose a position close to an undisturbed outlet free from electrical fluctuations.

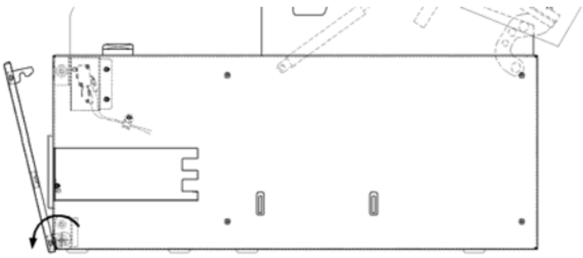
Never move the instrument after it is properly installed. Should movement or relocation of the instrument be necessary, a re-verification of the conditions listed in this paragraph would be required before using the instrument again. Whenever the instrument will not be used or an extended period of time it is suggested that it be disconnected from the power source and covered.

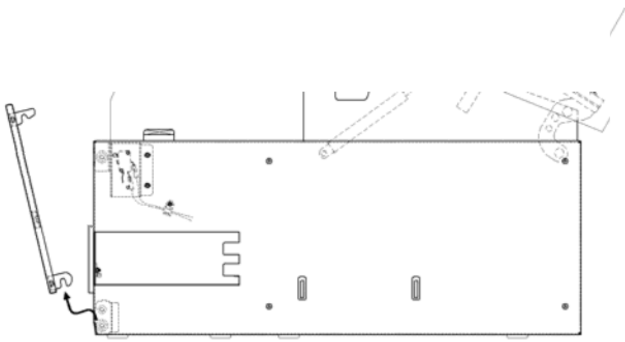
6. INSTALLATION

1. **Place the instrument on a solid and flat surface as described in the previous paragraph**
2. **Check the completeness of the supplied materials**
3. **Continue with the removal of the blocks of the Instrument as show in the following sequence:**









4. Assure that the power switch is in the OFF <<0>> position before continuing.
5. Executed connections with the external instruments.
6. Remove the tape blocking the window of the printer compartment and assure that the role of thermal paper is positioned correctly and free (free it from possible presence of elastic security band used during transport.
7. Install the rack insert extension as show in the photographic sequence.



8. Connect the plug of the power cable (use the cable that is supplied with the instrument) to the outlet on the right side of the power switch on the instrument itself (as shown in fig.) Connect the plug of the power cable to the power network.

7. Functional Startup Procedure

Once the instrument has been placed on the table of the laboratory and all the locks has been removed, please follow the procedure below for the functional startup of the instrument.

1. Switch ON the instrument.
2. Push the button "Open cover" end rise up the upper cover and check that it remains in the open position.
3. Remove the Front Panel end insert microswitches(Two metallic Keys, code 10345960), when you remove the panel the instrument show you the error messages (Use the Sound off button to silent the acoustical signal).
4. On the touch screen press the "Start" button to execute the complete Software and mechanical Reset(since is important that the cover is open you must push the microswitch when press the button).
5. Once the Reset procedure has been completed (the Stop button is active and the Start button is inactive), press the Stop button.
6. Load a Classifier Rack whit 1 sample(if in the laboratory the customer use the sarstedt tube is important that you insert this model of tube) in the position "7A" and when requested insert the ID code of the rack, or read it with the external barcode reader.
7. Enter in the Service Menu with the password "1-1-1-1-1-1".

8. Now from the service menu, in the "Procedures" section (located in the bottom-right corner of the display) end select the "TEST LOAD SAMPLE FROM RACK" end push exec.
   - If the clamp don't correctly goes on the tube you can change the parameter "CLAMPH RACK POS1" .
   - If the clamp don't correctly pick-up the tube from the rack(underneath the cap) you can change the parameter "LOAD CLAMPV RACK" ; <u>before making the adjustment to this parameter check the Home Offset of the unit</u>.
9. In the menu Procedures select the "TEST SAMPLE INSERTION" end push exec.
   - If you have a problem can change the parameter of vescube.ini "INSERTION CLAMPV CHAIN","INSETRION T VCHAIN OPEN CLAMP","INSERTION CLAMPV OVER CAP", "INSERTION T OVER CAP CLOSE CLAMP", "INSERTION CLAMPV CAP DOWN".
10. From the "Procedures" section "TEST SAMPLE EXSTRACTION" end push exec.
    - If there is e problem whit the positioning (horizontal) of the clamp(ex when the clamp go down it knock on the sensor) you must check the Home Offset of the unit.
    - If the clamp don't correctly pick-up the tube from the chain(underneath the cap) you can adjust the parameter "EXTRACTION CLAMPV CHAIN" for go further down it.
11. Now Select the Procedure "TEST UNLOAD SAMPLE TO RACK" and press "Exec" .
    - If there is a problem you can adjust the parameter "CLAMP H RACK POS1" end "UNLOAD T OPEN CLAMPV".
12. Exit from the Service menu by pressing "BACK".
13. Download the rack.
14. Press the Start Button to execute the Reset procedure.
15. Load a Classifier Rack, whit 5 samples, and when requested insert the ID code of the rack, or read it with the handheld barcode reader.
16. During the cycle check the correct working of the istrument:
    a. Identification/ Barcode reading
    b. Extraction/insertion of samples (clampV- clampH) (step 17)
    c. The correct work of mixer.
    d. Try to check the movement of the Reader Sensor (1 & 2) don't must touch the tube.
    e. Verify the correct positions of the Ejector.
17. At the end of the exam press Stop, and thet press "Download Classif".
18. Check the printout with all the tubes in the classifier rack, comparing the barcodes and the positions.
19. Remove the two metallic keys (code 10345960) from the microswitches and place the front panel in its correct position.
20. Start the Analytical Startup procedure.

8. ANALYTICAL STARTUP

Before testing the system it is important to remember the:

1- Volume range of the samples
2- Total number of labels.

Volume range of the samples*

Regarding the blood samples volume to be tested by the Ves-Matic Cube 80 the following procedure must be followed strictly:
In order to have reliable, accurate and precise results by this analytical system, the blood sample volume must fall within the following range

MINIMUM VOLUME = 1.5 ML
MAXIMUM VOLUME = 4.0 ML

This recommended volume is referred to all the different types of tubes we tested on the Ves-Matic Cube 80 (for example BD, Greiner, Terumo).

Software Release 2.24 points out the samples out of the above specified range showing “LOW” (volume sample less than ml.1,5) and “HIGH” (volume sample more than ml.4,0)

* This range don’t apply at the sarstedt tube.

Total number of labels

Labelling procedure and maximum number of labels compatible with the analytical system.

Ves Matic Cube 80 models are designed to work with a maximum of two labels attached to the same sample tube, but they must not be overlapping (Fig. 1).

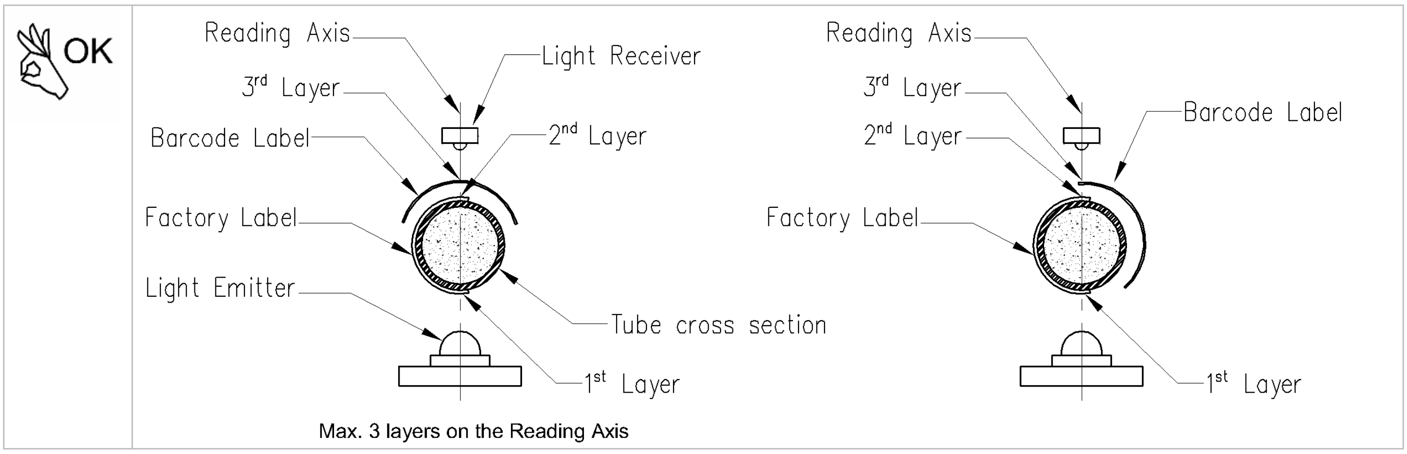


Fig.1 Labelling: Maximum number of label layers compatible with Ves-Matic Cube 80

The internal barcode reader, placed inside the Preparor Module, is:

- mechanically set to read labels attached to the tube at least mm.3 above the the start of bottom roundness (Fig. 2, ①).
- programmed to read barcodes placed at 90° degrees compared to the reading rays, that is the barcode must be placed to cross horizontally the tubes vertical axis (Fig. 2, ②).

The reader nevertheless can correctly read sloping barcodes, the slope must be within "-5" and "+5" degrees (Fig. 2, ③).

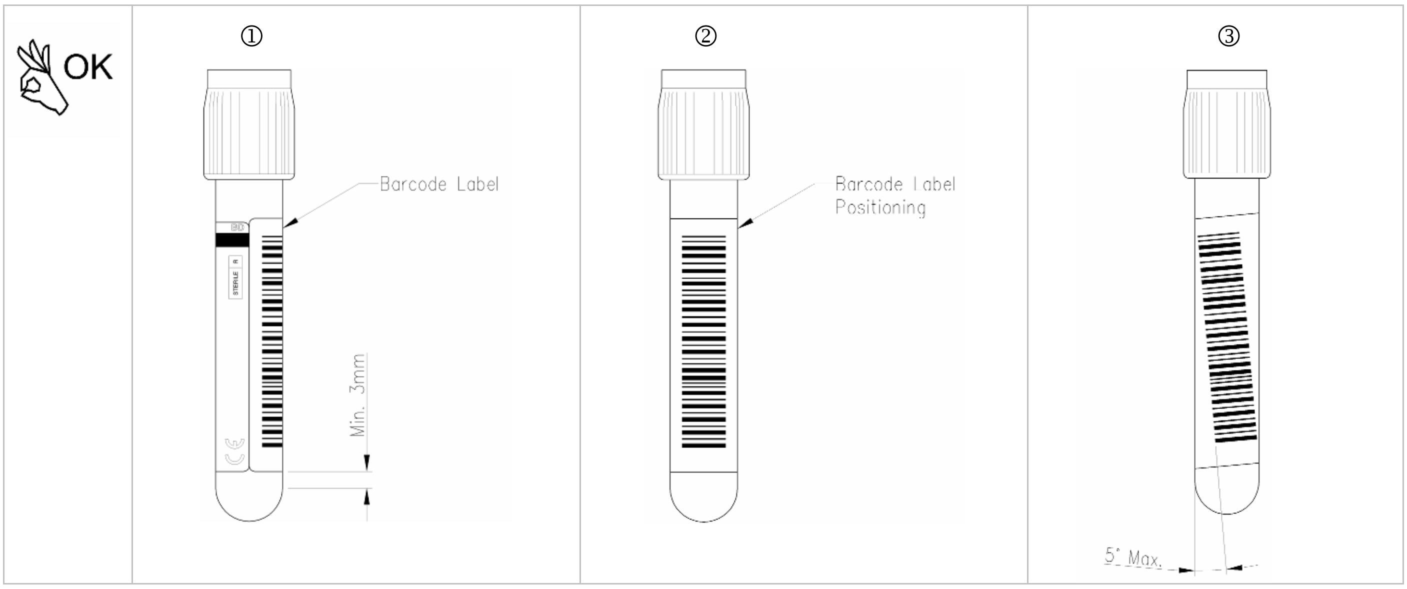


Fig.2 Labelling: compatible heights with Ves-Matic Cube 80

The reading group sensors are able to read correctly the sedimentation rate inside each sample, following the reading axis, passing through a maximum of three label layers: thus are allowed only two labels attached to the tube which must be staggered at least of 90° degrees (Fig. n°3).

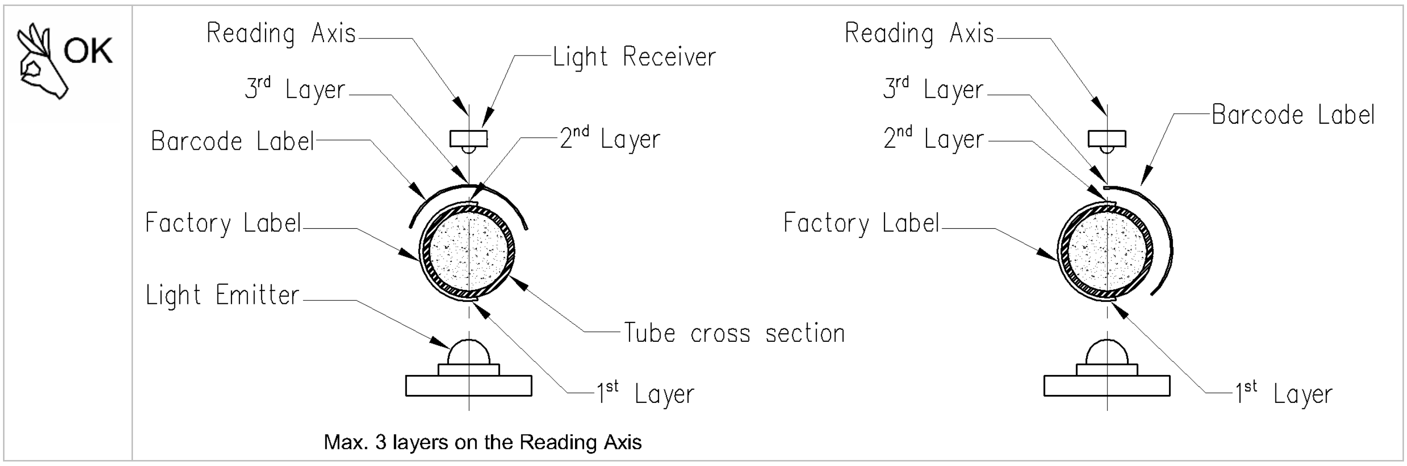
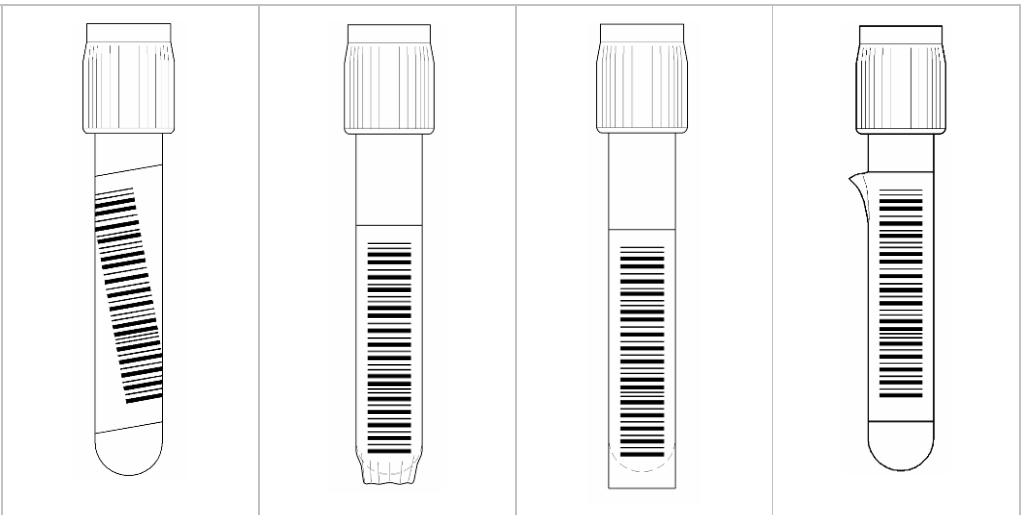


Fig.3 Labelling: Correct labels placing on sample tube

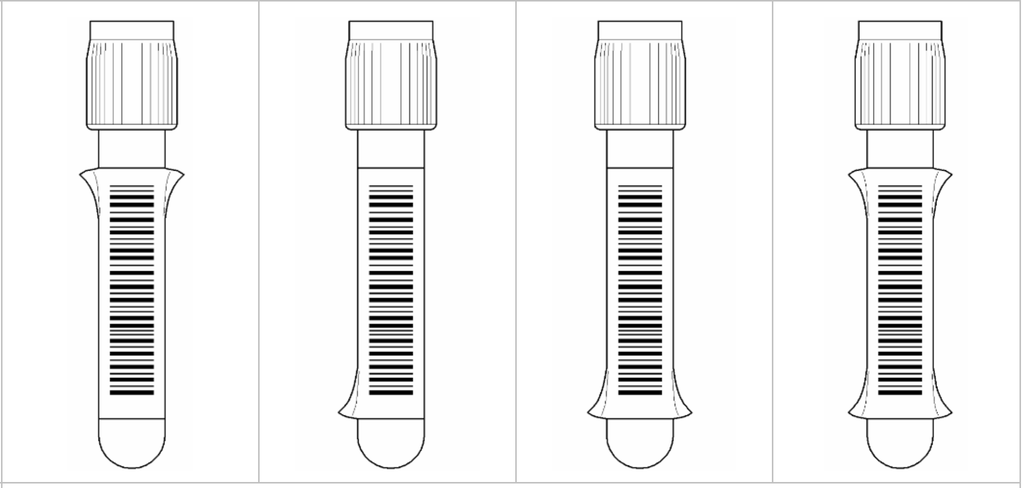
NOTICE: Verify, before loading the instrument, that the labels adhere perfectly to the tubes otherwise the unattached parts could cause frictions during the mechanical movements of the groups (especially inside the inserting, ejecting and sorting module), creating inserting and ejecting problems in the analitycal chain and possible blocks of the reading sensors.

In the following pictures some “WRONG” labelling examples are displayed. An incorrect labelling could cause mechanical blocks and/or reading problems to the Opto-Electronic Sensors.

NO



NO



NO

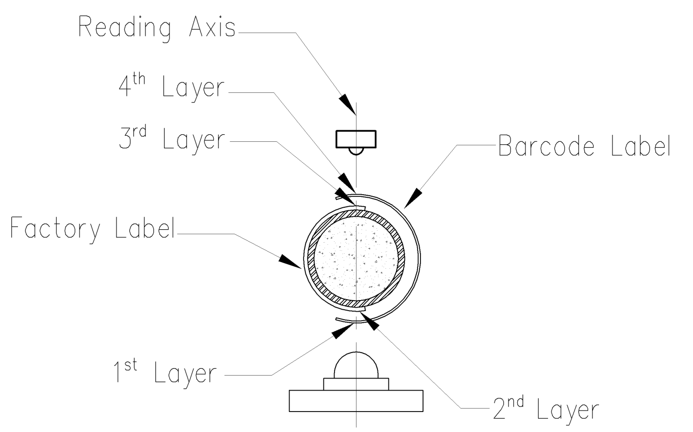


Fig.4 Labelling: Incorrect label for Ves-Matic Cube 80

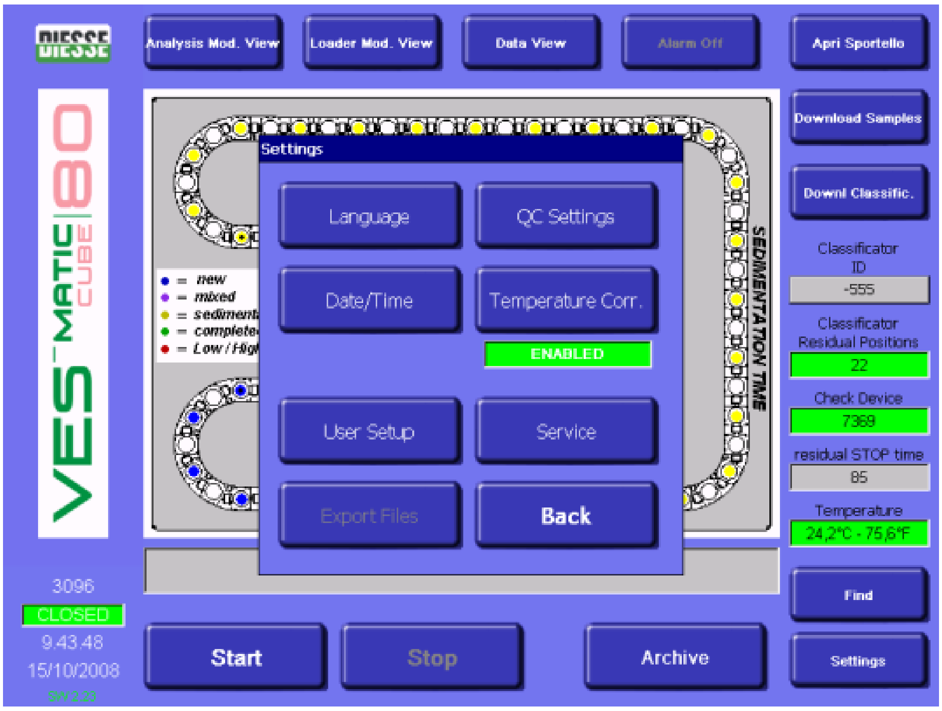
Materials

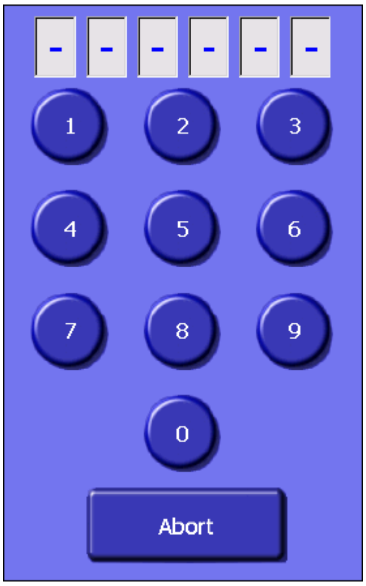
1 **Ves-Matic Cube 80**
2 **Fresh blood samples collected from the laboratory (suggested N° 50)**

Note:
Each instrument executes the analysis of the samples directly from test tubes being used on the blood cell counter in the laboratory, it is therefore not necessary to do a double drawing nor a transfer of biological material.

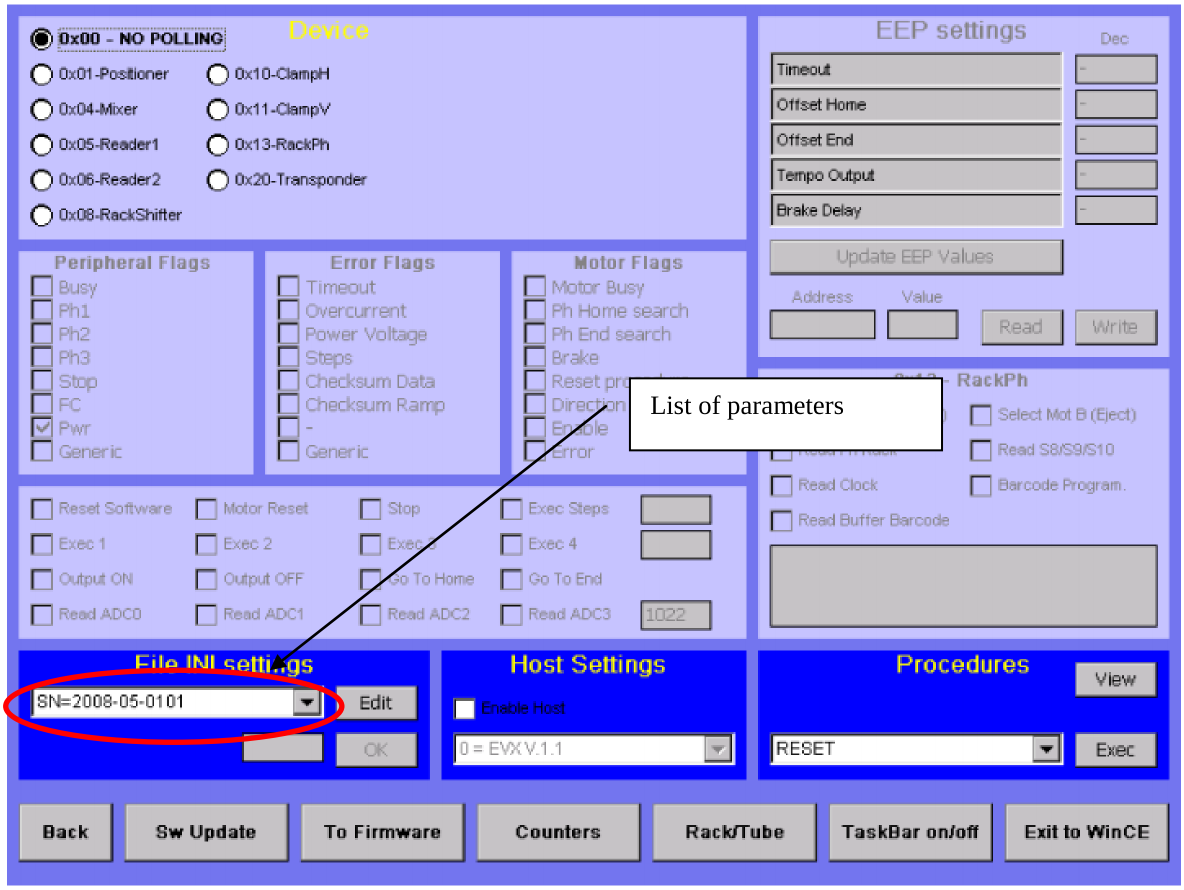
Procedure 1

Check VESCUBE.INI parameters.
Enter in the Service Menu' as described





Access password => "111111"



Read Parameters default values for “Vescube.ini”

[READ_PARAM]
DELTA_LIMIT=11
SH_THRESHOLD=100
START_POINT_M1=180
END_POINT_M1=0
START_POINT_M2=140
END_POINT_M2=0
DIFF_DIGITS=10
PERC_FILTER_MIN_ABS=20
DIGITS_RATE=50
M1M2_MAX_DIFF_ESR=20
PERC_CORR_ESR=60
RETRY_VES=140
NUM_MAX_RETRY_VES=0
MAIN_METHOD=1
M1M2_MAX_DIFF_ERR=1
SL_THRESHOLD=110
M3_WHIT_M2_NOT_ZERO=0
OVERDILL_ENABLE=0

Note :

-Using the Greiner Vacuette tubes end sarstedt tubes it is suggested to set the parameter **START_POINT_M2** as follows**:**
START_POINT_M2=120

- **END_POINT_M1** end **END_POINT_M2** must be equals.

Procedure 2

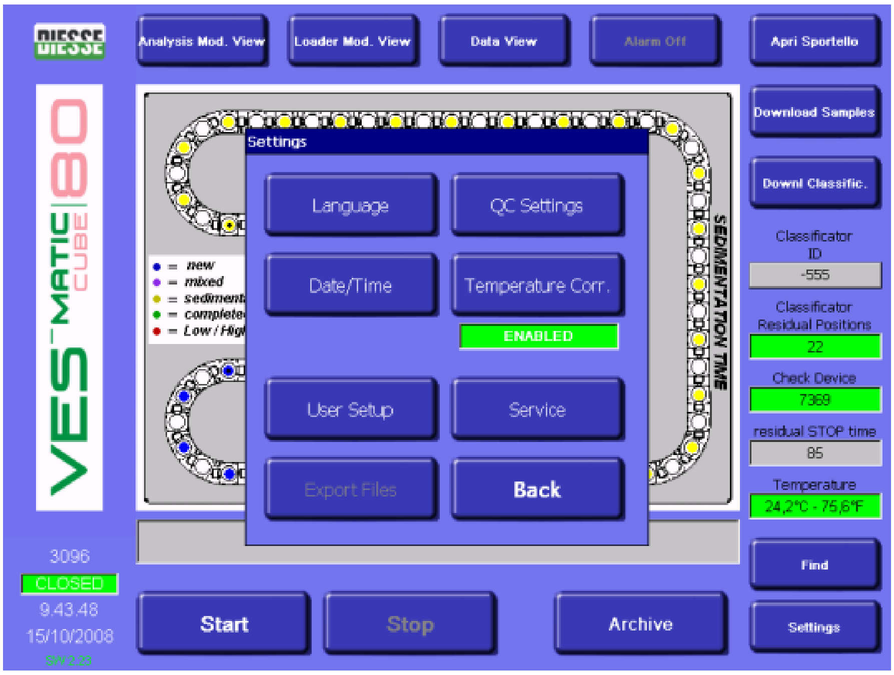
Log file activation.
It's very important to activate the **Log.txt** file .
In the Vescube.INI file check and eventually change the following parameter.

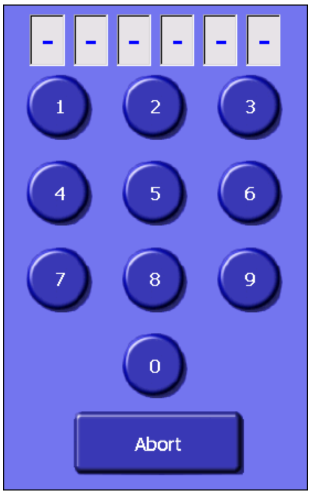
LOG_ENABLED=1

Procedure 3

Values for M1 and M2 activation .
Procedure directly show the values for M1 and M2 obtained from reader1 and reader2 on video during the run .

Open the Service Menu' as described





Access password => "131313"

After the password the software comes back to the main windows .

Procedure 4

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ANALYSIS RESULTS , CALCULATION ALGORITHMS and Error Evaluation

The reading sensors that measure the height of the blood inside the tubes are composed by an high power white led and an analogue light sensor.
The reading procedure executed by Reader 1 and Reader 2 is the following:

- *The Reading sensor goes to the end position, that corresponds to the top position, immediately under the cap of the tube.*
- *The LED is powered ON*
- *The sensor starts to move slowly from top to bottom.*
- *During the movement, at predefined fixed space intervals, the Light Sensor output signal is acquired and stored.*
- *The acquisition is completed when the sensor reaches the home position*
- *The Tablet PC requires to the Motor Driver Board that controls the Reader Unit the acquired light samples to elaborate them and to calculate the blood level.*

An example of the reading data is shown in the following images.

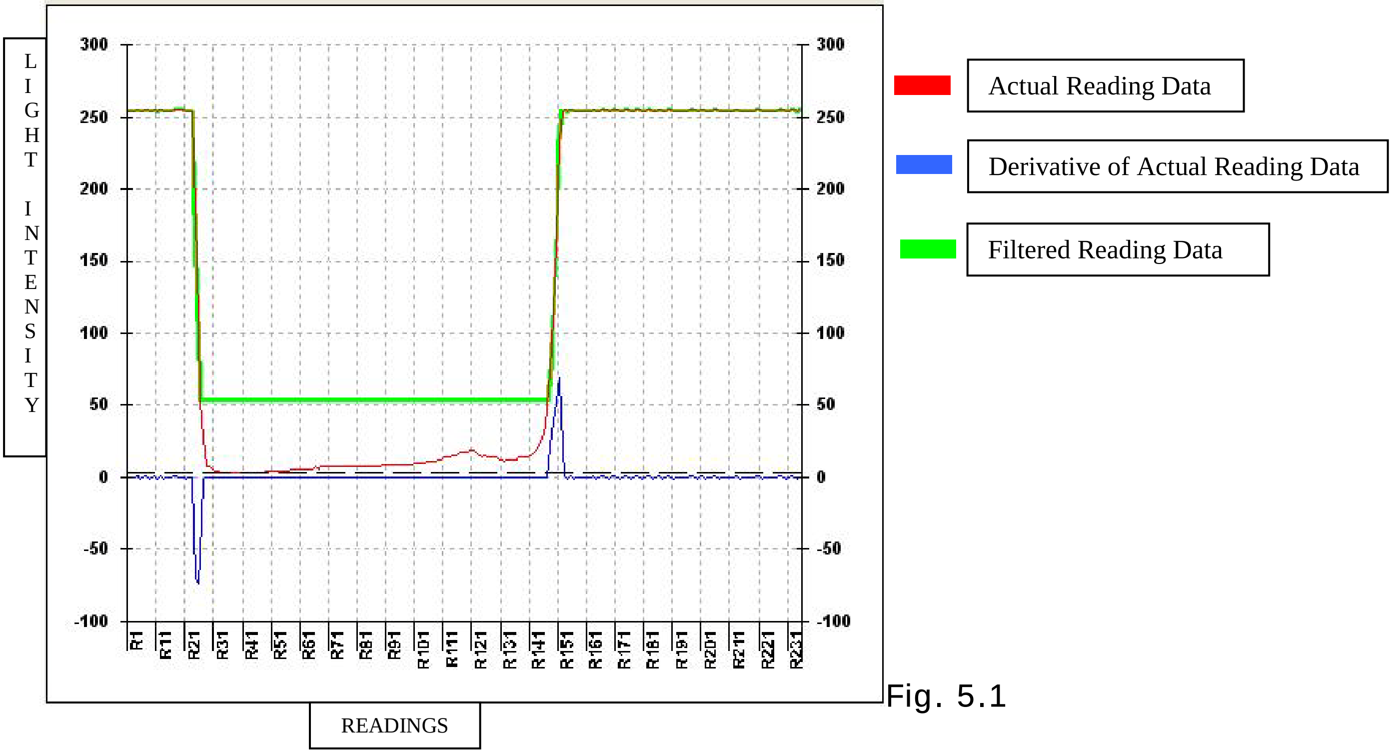


Fig. 5.1

In fig. 5.1 the typical reading curve is shown. On the vertical axis there is the Light Intensity measured by the light sensor. On the horizontal axis there are the various readings starting from the first (R1) that corresponds to the upper reading point, to the last (R231) that corresponds to the lower reading point.
In the next images the correspondence between the reading curve and the physical blood sample are explained in detail.

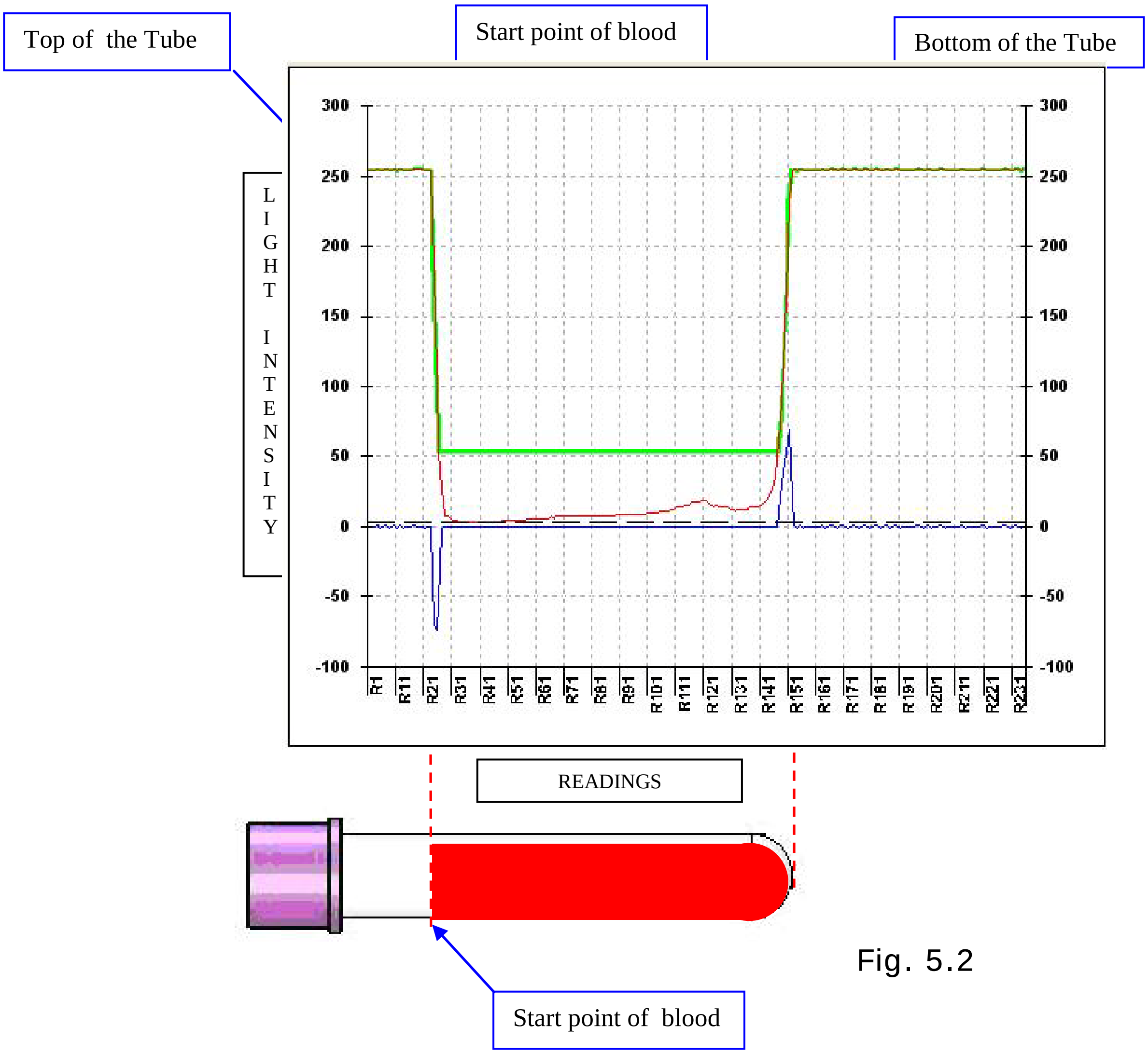


Fig. 5.2

In fig. 5.2 are explained the various points of the readings curve with their physical correspondence on the tube. The above curve is related to the First Reading of the sample, that is immediately after the Mixing. This is the Initial blood level.

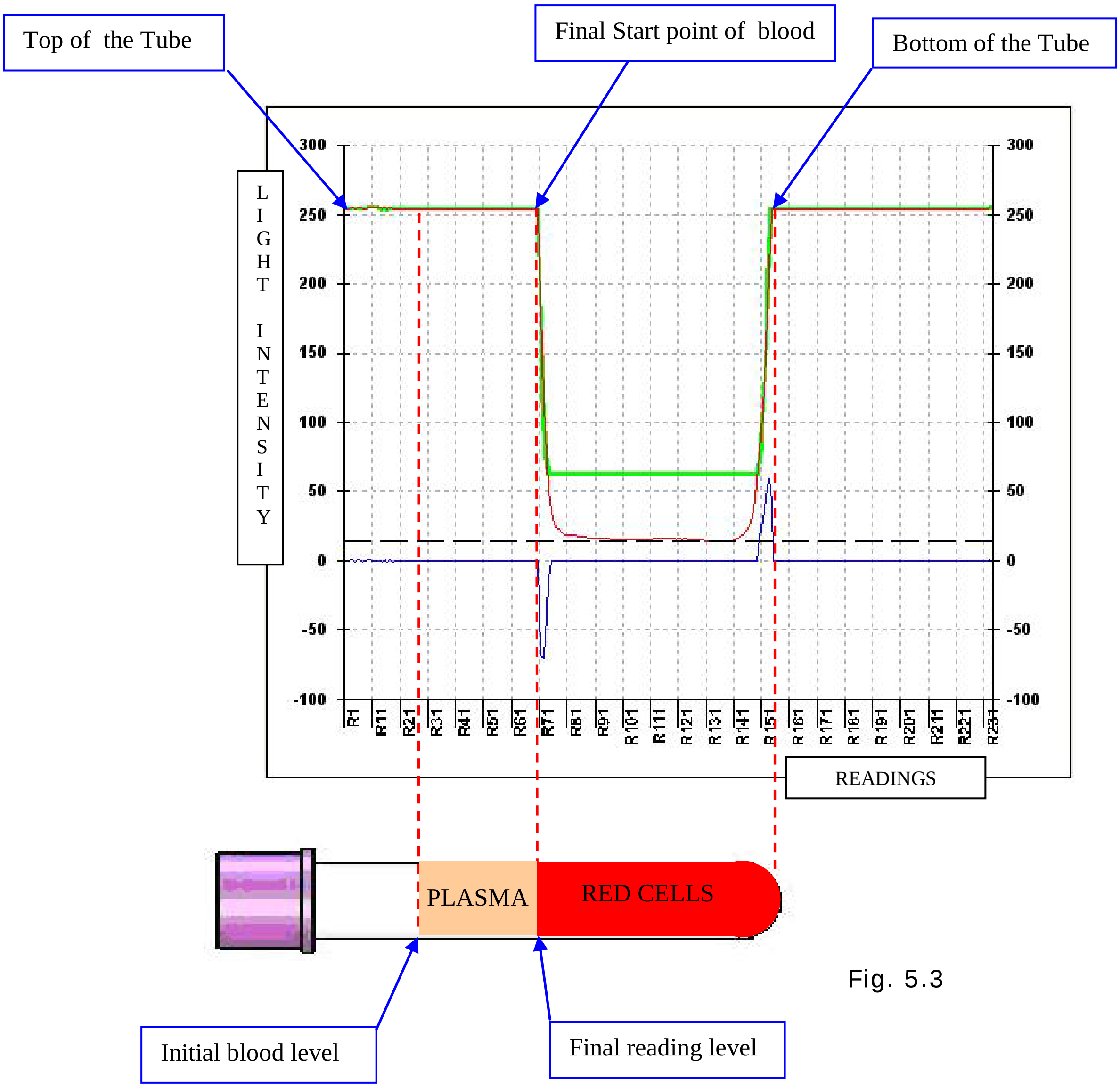


Fig. 5.3

In fig. 5.3 is represented the same sample of fig. 5.2, but read after the sedimentation time of 20 minutes. In this case the Red Cells are deposited on the bottom of the tube, and above them there is the Plasma. Plasma is completely transparent for the reading sensor, in fact the corresponding readings values are at the maximum level of light. This allows the software to detect the final reading level that is that of the Red Cells. Calculating the rate of level variation will bring to the final ESR value.

Detecting the "Start of Blood" Point

Two methods are used to elaborate the readings curves and detect the correct Start of Blood Point. The two methods are completely independent the one respect to the other, and are used to have a double security on the reliability of the readings, in fact if the points calculated by the two methods are different, a warning is signaled for that result to alert the user that it's an "Uncertain result".

Method 1

In Method 1 first of all the minimum light point is detected on the curve. Then using the parameter "PERC_FILTER" a limiting filter is applied to the curve so that all the values below the limit will be set equal to the limit itself.

The limit value is represented by the green line in the above figures.

Once that limit value has been found, and the curve has been filtered using this value, the curve is newly analyzed starting from the left-most point until the first point with light value equal to the filtering limit Value.

Then, starting from this point, going back in a right-to-left direction the algorithm looks for a step in the curve.
This step is assumed to be the Starting Point of blood.

This Step Point is the blood level in Method 1.

Applying this method for both Reader 1 and Reader 2 the two levels of blood are detected, and an ESR value is calculated, this ESR is the "Method 1 ESR value".

Method 2

Method 2 is based on the first derivative calculation for all the points of the curve. This calculation generates a new curve, the blue one on the above figures.
By analyzing this new curve, starting from the left-most point, the software looks for the first higher-rate falling edge, the point of this falling edge is assumed to be the Blood Level of Method 2.

Applying this method for both Reader 1 and Reader 2 the two levels of blood are discovered, and an ESR value is calculated, this ESR is the "Method 2 ESR value".

Method 3

Method 3 is based on a particular function of squaring signal to eliminate all spikes present. The software draws a new curve and after applies again M1 and M2 .

data
To activate the error message set the following param at 1.

M1M2_MAX_DIFF_ERR=1

In the Ves-matic cube it's possible to have 4 different alert data.

HIGH
LOW
Res*
ERR

After the first run is important to verify:

HIGH

For each **HIGH** message instead of the result check the blood's volume in the tube .
Procedure:
Fill a empty cell counter tube with 4.0 ml of water and compare this reference tube visually with all samples that have HIGH as result .
Is the Blood 's volume is lower than the water check the labelling condition.

LOW

For each LOW message instead of the result check the blood's volume in the tube .
Procedure:
Fill a empty cell counter tube with 1.5 ml of water and compare this reference tube visually with all samples that have LOW as result .
Is the Blood 's volume is higher than the water check the labelling condition .
Note : see appendix A for a suggested procedure to set sample LOW

Res*

ERR

Method 1 & Method 2 cross-verification

In the printout of the results, and in the data sent to the host computer the following criteria are applied:

If the difference between the two ESR calculated by Method1 and Method2 is lower than the M1_M2_MAX_DIFFERENCE the final ESR is the average value between those values, and is a valid result.

Otherwise if the difference is higher than M1_M2_MAX_DIFFERENCE the final ESR result will be the one calculated by the main method defined by the parameter MAIN_METHOD. If the ERROR_FLAG is set this final ESR value will be considered as an “Uncertain Value” and a “*” character will be printed near the result.
If the ERROR_FLAG is not set the ESR will be considered a valid result and printed out normally.

The “Uncertain results” will be sent to the host with the ESR value calculated and the “Abnormal Sample” flag set to one. The host will recognize Uncertain results by the simultaneous presence of a valid ESR value and the error flag.
On the other hand if the ESR value is 0, and the error flag is set, the Host computer will assume this as an ERROR.

If only one of the two methods is able to calculate an ESR, while the other returns a zero, the value calculated will be printed out, also if the method that calculated it is not set as the Main method. As in the case of high difference values if the ERROR_Flag is set the result will be treated as “Uncertain Value”, otherwise will be considered a valid result.

The two ESR values calculated by the two methods are processed as described in the following procedure:

If ESR(M1) is <> to 0 and ESR (M2) is <> to 0 and the difference between ESR(M1) and ESR(M2) is <= of a parameter in vescube.ini file , ESR is equal to the average of ESR(M1) and ESR(M2).

If ESR (M1) is = to 0 or ESR (M2) is = to 0 or the difference between ESR(M1) and ESR(M2) ERS is > of a parameter in vescube.ini file the software performs a M3 elaboration.

In this case the software will change the method (m1 or m2) unable to evaluate the sample with M3 and will perform again the elaboration as previous described.

NOTE: Parameters that affect the ESR final value

- DELTA_LIMIT=11: Minimum derivative value used by Method 2
- SH_THRESHOLD=100: Sample High detection threshold used by both methods
- START_POINT_M1=180: Right-most point analyzed by Method 1
- END_POINT_M1=0: Left-most point analyzed by Method 1
- START_POINT_M2=140: Right-most point analyzed by Method 2
- END_POINT_M2=0: Left-most point analyzed by Method 2
- DIFF_DIGITS=10: Value added to the LIMIT_VALUE to find the step in Method 1
- PERC_FILTER_MIN_ABS=20: Limiting filter applied in Method 1.
- DIGITS_RATE=50: In method 1 as alternative condition to identify the step
- M1M2_MAX_DIFF_ESR=20: Maximum difference between the two ESR values
- PERC_CORR_ESR=60: Correction Value or ESR used by both methods
- RETRY_VES=140: ESR final value above which the analysis is repeated
- NUM_MAX_RETRY_VES=0: number of retry in case of error or values > Retry_Ves
- MAIN_METHOD=1: Definition of the Main Method
- M1M2_MAX_DIFF_ERR=1: ERROR FLAG
- SL_THRESHOLD=110: Sample Low Threshold.
- START_POINT_M3=200: Right-most point analyzed by Method 3
- END_POINT_M3=0: Left-most point analyzed by Method 3

The following section provides information about how to resolve some problems.
We recommend, however, also consulting the manual to use the software ReadViwer 1.0..

When you change the parameters remember that END POINT M1 and END POINT M2 ought to be same.

You can download the software at the following address **:**
http://www.diesse.it/support/ves/vescube
Please note that access to the site is submitted to a password ; in case you do not have your password please contact **salesoffice@diesse.it**

After downloading unpack the file. Zip ; it is not necessary to create a specific directory.

Evaluation :

Flag type	Max %	If < max %	If > max %	
HIGH	2	ok	Check the tube If the check results	Volume and label

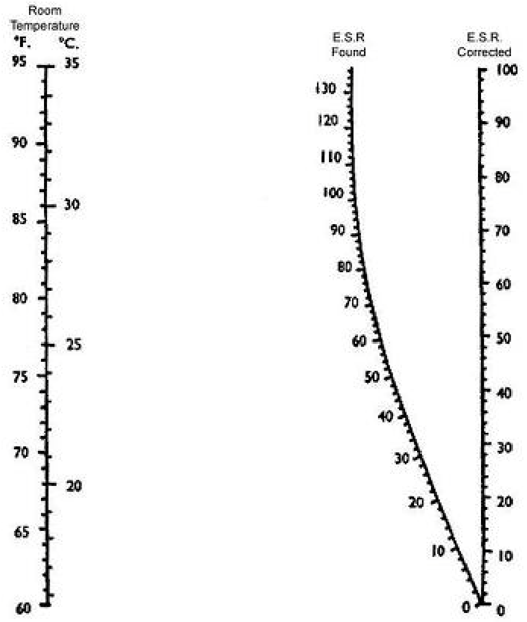
			visually ok send the log.txt file to the tech assistance .	
Low	2	ok	Check the tube If the check results visually ok send the log.txt file to the tech assistance .	Volume and label
Res *	2	ok	Check tube and M1 M2 reading; If the check results visually ok send the log.txt file to the tech assistance . If a lot of M2 values are 0 check the volume. If the sample volume is near to 1.5 ml try to increase START_POINT_M2= of 20 units ; otherwise if the sample volume is near to 4 ml decrease START_POINT_M2=of 20 units .	Label and calculation
ERR ERR	2	ok	Check tube and M1 M2 reading If the check results visually ok send the log.txt file to the tech assistance .	Label and calculation

Procedure 5

Precision between RUNS

All samples must be processed TWO TIMES using the same Ves-Matic Cube 200 with temperature correction active.

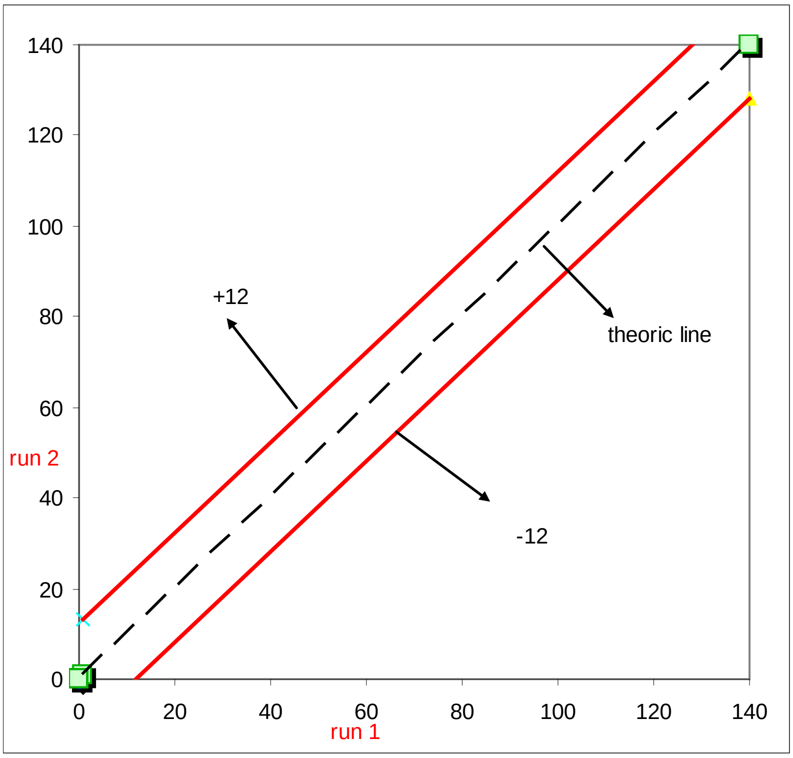
The instrument, which is designed with the temperature correction activated, relates the results to a temperature of 18°C according to Manley's Nomogram (Graph 1.1).



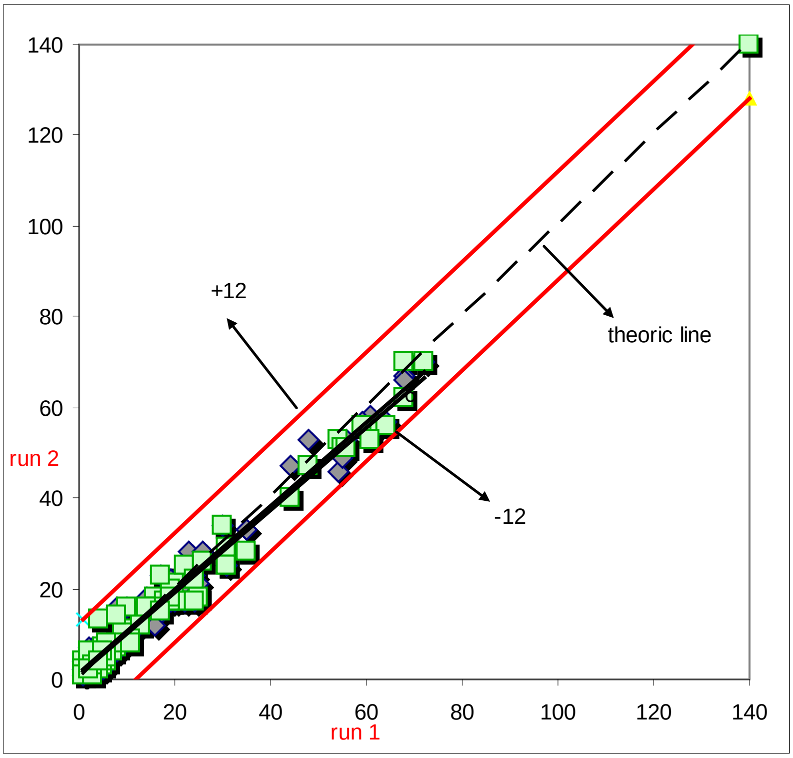
Graph 1.1 Manley's Nomogram

RESULTS

To evaluate the precision between runs use a very simple grah. like the one in the follwing figure



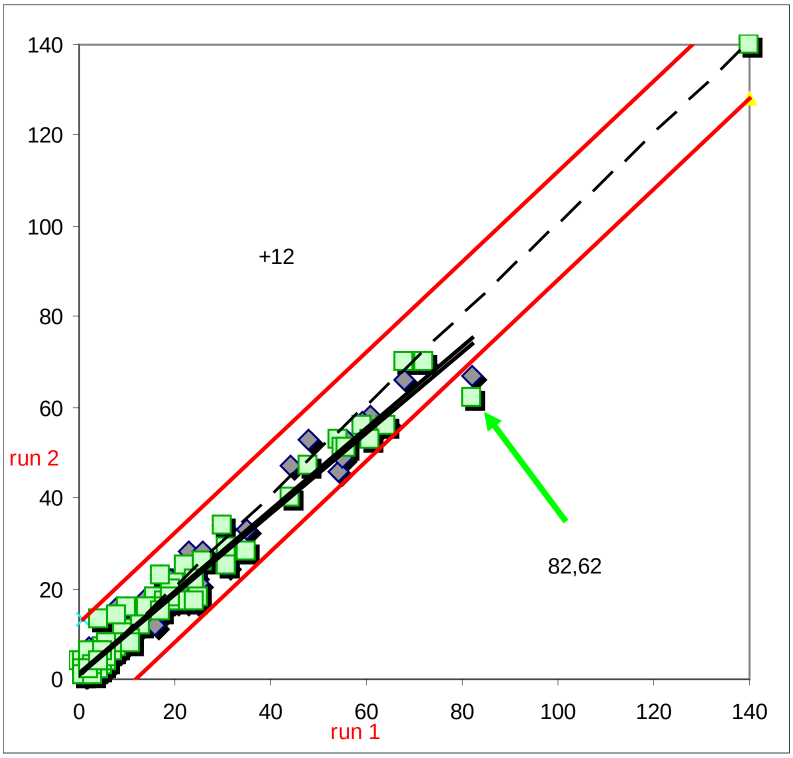
All samples have to stay within the red limits .



If one or more samples are out of range is important to evaluate the patological signifiance:

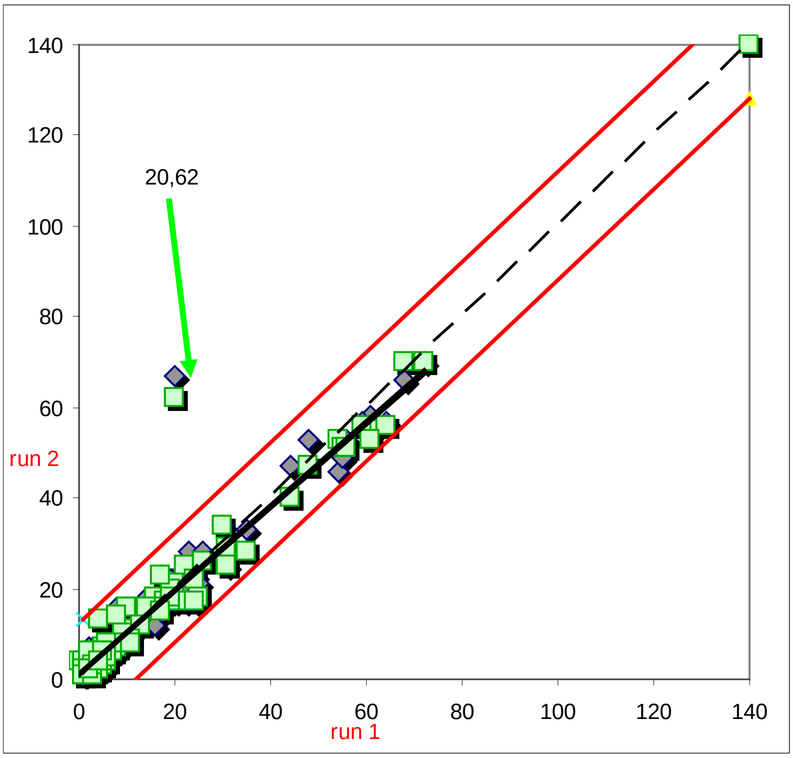
e.g.

case 1



In this case it is possbile ot accept the test as valid since there is no risk of invalidating the clinical meaning of the test

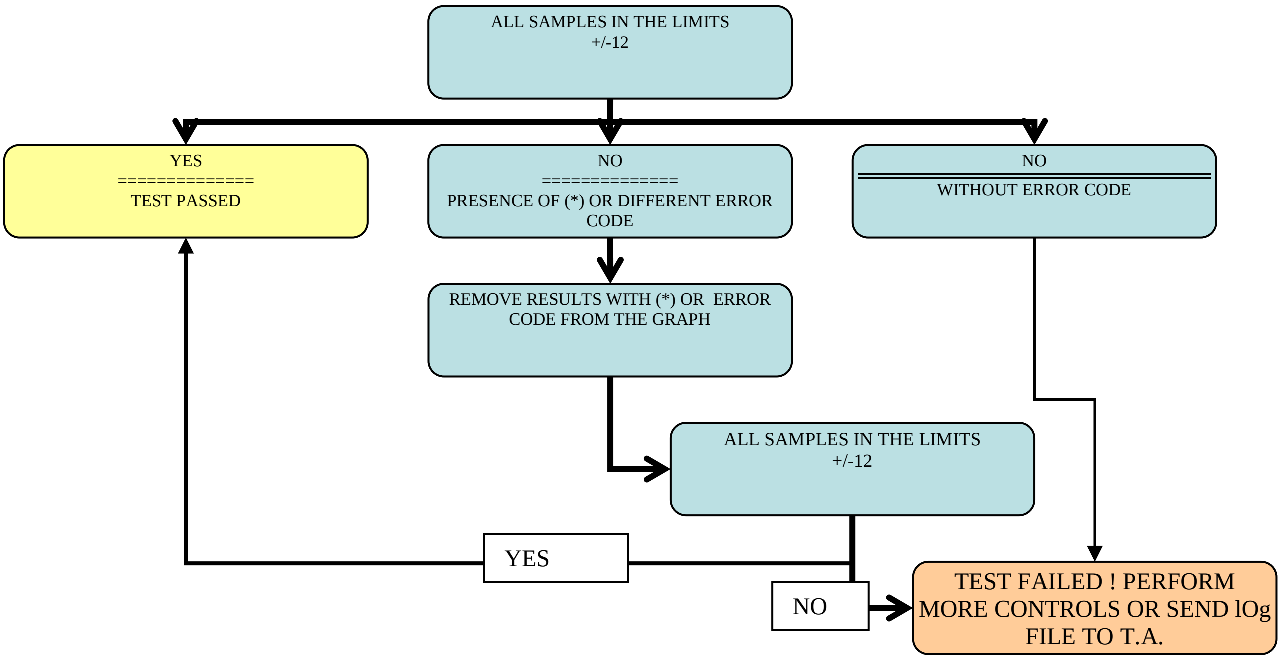
Case 2



In this case the test has to be considered not correct since the repetition of a sample changes its state, from normal to pathologic and vv.

Note 1:
Before processing the samples assure that they are:
a) fresh or stored at 4°c
b) wait for them to arrive at room temperature
WARNING:
Avoid analyzing samples directly from the fridge, the subsequent warming up will cause the test to be poorly reproducible for a progressive modification in the behavior of the sedimentation.
Note 2:
Before reporting the obtained values in a test of reproducibility pay attention of possible error flags present. (see paragraph on errors)

Use the following evaluation chart.



Appendix A

Suggested procedure to Set sample LOW code .

1) Prepare 3 tubes with 1,5 mL.of blodd

2) Enable the reading view page (insert the password 131313 like when you enter in the service menu), before to press START.(" SM MODE ").

3) after the mixing of the samples, check the values for READ1
The value for SL_THRESHOLD parameter will be the average obtained value from vescube minus 5 units .
E.g 131, 128, 133. set in vescube.ini file ,SL_THRESHOLD = 125.

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Francesco Cocola